

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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HEATHER SPRACKLEN and JOE *
HIGGINS, on Behalf of M.H., *
a Minor, *

Petitioners,

v.

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
Respondent. *

* * * * *

No. 16-559V
Special Master Christian J. Moran

Filed: July 31, 2019

Entitlement, diagnosis,
acute disseminated
encephalomyelitis (ADEM)

John Robert Howie, Jr., Howie Law, PC, Dallas, TX, for petitioners;
Darryl R. Wishard, United States Dep't of Justice, Washington, DC, for
respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Heather and Joe Spracklen alleged that the mumps-measles-rubella (“MMR”) vaccine caused their daughter, M.H., to suffer acute disseminated encephalomyelitis (“ADEM”). Pet’rs’ Prehear’g Br., filed Nov. 20, 2018, at 13. To assist them, the Spracklens retained a neurologist, Steven Lovitt. The Secretary disagreed with the allegations and retained a pediatric neurologist, Peter Bingham.

Due to the dispute between the experts, the case proceeded to a hearing, which was held in Dallas, Texas, on February 8, 2019. At the end of the hearing, the undersigned presented preliminary views but allowed the parties to file briefs

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

tightly focused on whether M.H. suffered from ADEM. The parties have done so, and both attorneys advocated effectively.

Establishing by preponderant evidence that M.H. suffered from ADEM is a required part of the Spracklens' case. However, the evidence considered, as a whole, does not support this finding. Thus, the Spracklens have not established that they are entitled to compensation.

I. Brief Overview of M.H.'s Chronology²

Ms. Spracklen gave birth to M.H. on April 26, 2012, a date that was earlier than expected. M.H. suffered from intrauterine growth restriction and was born with a low birth weight: 2,100 grams. Exhibit 4 at 31; exhibit 5 at 8.

For the next year, M.H. was developing normally. When she had her well-baby checkup shortly after turning one year old, she passed the 12-month milestones. Exhibit 6 at 13-18. In this appointment, which was on May 10, 2013, she received the allegedly causal MMR vaccine. Exhibit 6 at 1, 15, 17.

On May 27, 2013, M.H. seemed to go limp when her mom was tossing her into the air. The Spracklens brought her to an emergency room at Stillwater Medical Center. A nurse noted that M.H. was fussy with a weak cry. The doctor indicated that M.H. had a shoulder problem. Exhibit 5 at 55-59. After being discharged home, M.H. slept restlessly.

The next morning, when Mr. Spracklen picked M.H. up from bed, she seemed to be having a seizure. Her parents rushed her to a nearby firehouse. The firefighters called an ambulance and the ambulance brought M.H. to Stillwater Medical Center. Exhibit 11.

M.H. remained at Stillwater Medical Center for a few hours. Medical personnel provided some initial care to M.H. and then determined that M.H. should be transferred to a facility offering more enhanced medical services, Saint Francis Hospital. See exhibit 5 at 107. The reason for the transfer was that M.H. had limited range of motion. She could not move her arms or legs and she could not lift her head. Id. at 73, 103.

² The undersigned has reviewed all the records. However, this decision does not recite all of them.

In Saint Francis Hospital, M.H. underwent a series of MRIs. The MRI of her brain was normal. The MRI of her cervical spine showed a very large lesion. Exhibit 7 at 68-69 (May 29, 2013).

A neurologist, David Siegler, saw M.H. on May 29, 2013. Dr. Siegler noted that M.H. was suffering from quadriplegia. Dr. Siegler was concerned about an infectious or inflammatory process and started steroids. Exhibit 7 at 16-18.

After M.H. completed a 5-day course of steroids, Dr. Siegler saw her again on June 3, 2013. M.H. had weakness in all her extremities. Dr. Siegler diagnosed M.H. as suffering from an inflammatory myelitis and recommended intravenous immunoglobulin. Exhibit 7 at 18-19.

On June 7, 2013, an infectious disease specialist, Michael Chang, saw M.H. He recorded that M.H. had not suffered any illness preceding the onset of her paralysis. Dr. Chang agreed with the diagnosis of transverse myelitis. Dr. Chang also stated that he would report M.H.'s case to the Vaccine Adverse Events Reporting System (VAERS) although it was unlikely for the vaccine to have caused her condition. Exhibit 7 at 22-24.

The doctors repeated the MRIs on June 10, 2013. The brain MRI continued to show no abnormality. The cervical spine was improved as it showed minimal signal abnormality. Exhibit 7 at 75-77.

Saint Francis discharged M.H. on June 11, 2013. In reciting M.H.'s history, the author of the discharge report mentions that M.H. had received immunizations. But, the writer did not directly link the vaccinations to M.H.'s conditions. "The patient had a significant workup for what seems to be an infectious or inflammatory process causing her acute onset of flaccid paralysis." "As discussed with infectious disease and neurology, it seems like transverse myelitis possibly from an inflammatory or infectious process." Exhibit 7 at 15.

From Saint Francis, M.H. went to the Children's Center Rehabilitation Hospital. Upon admission, a doctor from the Children's Center, Justin Ramsey, authored a report about M.H.: "This is a young woman. I am somewhat perplexed by her history. Working diagnosis from Saint Francis is transverse myelitis." Exhibit 9 at 192.

To assist in M.H.'s care, Dr. Ramsey requested that a pediatric neurologist from Oklahoma University see her. This physician was Gabriella Purcarin. In Dr. Purcarin's initial report, she recorded that before the onset of M.H.'s paralysis, "she had 2 weeks of increased irritability and low grade fevers, after her one year

vaccinations.” Exhibit 10 at 169. Dr. Purcarin’s diagnosis for M.H. was: grand mal seizure, quadriplegia, myelopathy which was likely autoimmune inflammatory.” Id.

M.H. remained in the Children’s Center Rehabilitation Hospital until July 19, 2013. At the time of discharge, Dr. Purcarin was planning to see M.H. in late August. Exhibit 9 at 9-19.

Within a week of being discharged from the rehabilitation facility, M.H. saw her usual pediatrician, Scott Martin. Dr. Martin noted that M.H. had weakness secondary to transverse myelitis. Exhibit 6 at 18.

On July 30, 2013, M.H. had a febrile seizure lasting approximately one minute. Exhibit 5 at 573. This seizure was in the context of a urinary tract infection. Exhibit 7 at 441.

Following this seizure, M.H. returned to Dr. Martin. He stated M.H. had “recent paralysis and transverse myelitis without clear source.” He planned to discuss how to control M.H.’s seizures with a neurologist. Exhibit 6 at 22.

The scheduled follow-up with Dr. Purcarin occurred on August 28, 2013. Preliminarily, M.H. had another MRI, which showed significant improvement in her cervical spine. The radiologist who interpreted the MRI listed potential diagnoses as idiopathic transverse myelitis, ADEM, West Nile, and neuromyelitis optica. Exhibit 10 at 28. Dr. Purcarin noted M.H.’s improvement. Id. at 147.

Approximately five months later, M.H. returned to Dr. Martin for her two-year-old well-child visit. Exhibit 6 at 28 (Feb. 3, 2014). Dr. Martin commented that M.H.’s “growth has slowed over [the] last year due to her difficulties post transverse myelitis.” Id. at 31. Dr. Martin also recorded that M.H. was failing some milestones relating to motor coordination. However, M.H. was meeting the milestones relating to expressive language. Id. at 29.

On August 26, 2014, Dr. Purcarin also made a notation about M.H.’s language. Dr. Purcarin wrote: “Speech and language normal for her age.” Dr. Purcarin concluded that M.H. had no new neurologic deficits and Dr. Purcarin’s impression was “acute myelopathy, most likely transverse myelitis.” Exhibit 10 at 91.

For a well-child visit at 2.5 years old, Dr. Martin saw M.H. on November 12, 2014. In addition to noting M.H.’s muscle weakness, Dr. Martin added that

M.H.'s speech was delayed. Exhibit 5 at 557. This referral seemed to lead to speech therapy for M.H.

The most recently filed records include an Individualized Education Plan ("IEP") that M.H.'s school issued on March 27, 2018. The educators noted that M.H. has some great academic skills. She was also receiving speech language services, occupational therapy services, and physical therapy services. Exhibit 66 at 18.

II. Standards for Adjudication

Petitioners are required to prove their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty). In this regard, "close calls regarding causation are resolved in favor of injured claimants." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

When there is some dispute about a petitioner's diagnosis, special masters may find whether a preponderance of evidence supports any proposed diagnosis before evaluating whether a vaccine caused that illness. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345-46 (Fed. Cir. 2010).

III. Analysis

The evidence fails to show that M.H. suffered ADEM. The reasons for this finding are: (1) her treating doctors did not diagnose M.H. as suffering from ADEM, (2) the medical records do not support Dr. Lovitt's opinion that she suffers from ADEM, and (3) M.H.'s current disabilities are not necessarily due to ADEM. These reasons are explained below.

A. The treating doctors did not diagnose M.H. with ADEM.

The opinions of treating doctors can be quite probative. Cappizano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See McCulloch v. Sec’y of Health & Human Servs., No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec’y of Health & Human Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26, 2016).

Here, the treating doctors consistently diagnosed M.H. as suffering from transverse myelitis. None of the doctors diagnosed her with ADEM. At best, ADEM appeared as an item in their list of differential diagnoses early in her disease course. See exhibit 7 at 8 (ADEM). Following the August 28, 2013 MRI, ADEM was also included among the differential diagnoses. Exhibit 10 at 28. However, ADEM never advanced beyond a possibility among multiple possibilities. Instead, as noted in the presentation of M.H.’s chronology, many doctors diagnosed her as suffering from transverse myelitis without diagnosing her as suffering from ADEM.

In short, these multiple reports collectively constitute strong evidence that transverse myelitis, not ADEM, is the appropriate diagnosis for M.H.

B. Dr. Lovitt’s opinion that M.H. suffered from ADEM is not consistent with the medical records.

The Spracklens’ expert, Dr. Lovitt, reviewed the medical records and formed an independent opinion that M.H. suffered from ADEM. Exhibit 15 at 7. However, the Secretary’s expert, Dr. Bingham, disagreed. Exhibit A at 6. Although there was a dispute about whether M.H. suffered from ADEM, there was an agreement that Krupp set forth the diagnostic criteria for ADEM. See Pet’rs’ Prehear’g Br., filed Nov. 20, 2018, at 12-13; Resp’t’s Prehear’g Br., filed Dec. 12, 2018, at 7.³

³ Lauren B. Krupp et al., Consensus definitions proposed for pediatric multiple sclerosis and related disorders, 68 (Suppl 2) *Neurology* S7 (2007), filed as exhibit 18.

The complete diagnostic criteria are set forth in the appendix. Dr. Lovitt emphasizes that the diagnostic criteria allow for exceptions. Tr. 78; see also exhibit 18 at S11. For purposes of this decision, the two relevant criteria are MRI imaging and the presence of an encephalopathy. Tr. 63.

MRI imaging. During her stay in Saint Francis Hospital, M.H. underwent two MRIs. Exhibit 7 at 68-69 (May 29, 2013), at 75 (June 11, 2013). Both brain MRIs failed to detect any abnormalities.

The failure of both MRIs to reveal any problems within M.H.'s brain weighs heavily against a finding that M.H. suffered from ADEM. In his career, Dr. Lovitt has not seen a case of ADEM with a negative MRI. Tr. 262.

In lieu of MRI findings, the Spracklens and Dr. Lovitt appear to offer an alternative way of demonstrating that M.H.'s brain was damaged. See Pet's Prehear'g Br. at 21. They point to records showing that M.H. had problems controlling her tongue and swallowing. The nerves that control the tongue and swallowing originate in the brain stem. Tr. 255.

Determining the extent of any problem with tongue control or swallowing – or even if M.H. were having a problem – is difficult. On the day of the MMR vaccination, M.H. was drinking milk and eating table food. Exhibit 6 at 13. But, after vaccination, the records about eating, swallowing, and tongue control vary.

The Spracklens emphasize that on her admission to the Children's Center Rehabilitation Hospital, Dr. Ramsey indicated that M.H. was having trouble controlling her tongue. Exhibit 9 at 2-3. However, this is the only mention of a problem with tongue control in the record. See Tr. 173. In the Children's Center, M.H. seems to have one episode of coughing while eating. Exhibit 9 at 13, 248.

Previously, at her stay in Saint Francis Hospital, there is no record of swallowing problems. Tr. 59 (Dr. Lovitt). Actually, some records show normal swallowing and/or a normal diet. See, e.g., exhibit 7 at 144, 323, 60.⁴

Overall, evidence that M.H. suffered from an injury in her brain is not persuasive. The MRIs did not detect any lesions. Importantly, M.H. underwent two MRIs, approximately two weeks apart. The repetition blunts the persuasive value of any argument that the first MRI was administered too quickly to see any

⁴ Somewhat inconsistently, a record from the Children's Center indicates that when M.H. was at Saint Francis Hospital, M.H. coughed during oral intake. Exhibit 9 at 245.

changes. Because the diagnostic criteria from Krupp requires positive findings on an MRI, the negative MRIs weigh strongly against the ADEM diagnosis. See Tr. 78 (Dr. Lovitt acknowledging that M.H. does not meet the formal criteria for ADEM because of the lack of findings on her MRIs).

Encephalopathy. Krupp specifically defines encephalopathy as either “behavioral change e.g., confusion, excessive irritability,” or “alteration in consciousness e.g., lethargy, coma.” Exhibit 18 (Krupp) at S8. The experts disagreed as to the expected degree of consistency in presentation. Dr. Lovitt opined that the symptoms constituting encephalopathy could fluctuate. Tr. 108. But, Dr. Bingham disagreed. Tr. 174.

Initially, reports about M.H.’s behavior were inconsistent both internally and externally. An example of an internally inconsistent record comes from when Mr. and Ms. Spracklen brought M.H. to the fire station before EMTs brought her to Stillwater Medical Center. M.H.’s score on the Glasgow coma scale was the maximum rating: 15. Yet in the same report, an EMT described her as being alert, verbal, in pain, and unresponsive. Exhibit 11 at 2. These data points are not congruent. Tr. 106, see also Tr. 192, 231.

Likewise, on May 28, 2013, two nurses described M.H. as “lethargic” and “listless.” Exhibit 5 at 115-16. Dr. Lovitt saw these signs as consistent with an encephalopathy. Tr. 57. However, Dr. Bingham offered other explanations for M.H.’s behavior. Tr. 194, 234. Later, M.H. also took a drink from her bottle, exhibit 5 at 115-16, an action that seems inconsistent with an encephalopathy.

Regardless, these instances seem too isolated to support a finding of encephalopathy. These reports must be placed in context of M.H.’s entire hospitalization and rehabilitation for her transverse myelitis. See Tr. 202 (Dr. Bingham opining that some abnormal behavior may have been because she was sick). At Saint Francis, nurses checked M.H. often with their records running nearly two hundred pages. The nurses appear not to worry about M.H. being encephalopathic. Exhibit 7 at 75-267. On the two occasions when a neurologist saw her, the neurologist did not diagnose encephalopathy. Exhibit 7 at 16-18, 18-19.

For these reasons, Dr. Lovitt has not offered a persuasive opinion for overturning the views of the doctors who treated M.H. and did not diagnose her as suffering from ADEM.

C. M.H.'s current condition does not mean she suffered from ADEM.

M.H.'s medical history did not stop when she was discharged from rehabilitation on July 16, 2013. Dr. Lovitt relies upon M.H.'s current disabilities to support an argument that the diagnosis of transverse myelitis is not sufficient to explain everything wrong with M.H. Tr. 77.

M.H.'s transverse myelitis is marked by an extensive lesion in her spinal cord. This location means the lesion causes motor problems in her extremities. But, a spinal cord lesion would not directly impair the nerves above the lesion, including the nerves responsible for language.⁵

M.H. currently has a problem with language. Her school system provides speech language services because "She continues to show moderate delays in her receptive and expressive language skills." Exhibit 66 at 18 (2018 IEP). Based upon records from M.H.'s pediatrician, Dr. Martin, and M.H.'s neurologist, Dr. Purcarin, the Secretary asserts M.H.'s language problem appeared between August 26, 2014, and November 12, 2014. Resp't's Posthear'g Br., filed Mar. 11, 2019, at 2, citing exhibit 6 at 28 and exhibit 10 at 91, 129. The Spracklens did not counter this persuasive analysis. See Pet'rs' Reply, filed Mar. 20, 2019.

This onset of expressive language problems means that 15-18 months had passed after the May 10, 2013 vaccination. It seems unlikely that a vaccination would cause a problem that surfaced more than one year later. This delayed onset is also inconsistent with how ADEM usually appears – acutely.

In summary, the Spracklens did not establish that M.H. suffered from ADEM. A finding of ADEM would implicitly upset the diagnoses of the doctors who treated M.H. Such a finding would also be inconsistent with the preponderant evidence contained in the medical records.

Without the diagnosis of ADEM, there is no reason to analyze the Althen prongs for a connection between the vaccinations and ADEM. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) ("If a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult)

⁵ Dr. Bingham theorized that M.H.'s lack of motor coordination affects how she interacts with the environment and this diminished interaction could contribute to language problems. Tr. 188.

question whether there is a medical theory”); Bell v. Sec’y of Health & Human Servs., No. 13-709V, 2016 WL 8136297 (Fed. Cl. Spec. Mstr. Dec. 1, 2016) (determining that the vaccinee did not suffer from ADEM and denying entitlement to compensation).⁶

Conclusion

At the hearing, the Spracklens displayed great care and concern for their injured daughter and M.H.’s condition merits sympathy. However, Congress expected Special Masters to decide cases based upon the evidence, not sympathy. Here, despite the able advocacy from their attorney, the Spracklens have not presented preponderant evidence that M.H. suffered ADEM. Thus, they are not entitled to compensation. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

⁶ At hearing, Dr. Lovitt supported a theory that the MMR vaccine can cause ADEM with literature. See, e.g., exhibit 88 (PowerPoint presentation summarizing medical literature) at 17-29. In contrast, Dr. Lovitt’s testimony about whether MMR vaccine can cause transverse myelitis was fleeting at best. See, e.g., id. at 30, Tr. 69 (the link between vaccination and transverse myelitis has not been studied adequately). Consequently, the undersigned tentatively found that the Spracklens had not advanced the alternative theory that MMR vaccine can cause transverse myelitis with any persuasiveness. Tr. 280-84.

Appendix: Diagnostic Criteria for ADEM
(Source: exhibit 18 (Krupp) at S7-8)

1. A first clinical event with a presumed inflammatory or demyelinating cause, with acute or subacute onset, that affects multifocal areas of the CNS. The clinical presentation must be polysymptomatic and must include encephalopathy, which is defined as one or more of the following:

a. Behavioral change, e.g., confusion, excessive irritability OR

b. Alteration in consciousness, e.g., lethargy, coma;

2. Event should be followed by improvement, either clinically, on MRI, or both, but there may be residual deficits;

3. No history of a clinical episode with features of a prior demyelinating event;

4. No other etiologies can explain the event;

5. New or fluctuating symptoms, signs, or MRI findings occurring within 3 months of the inciting ADEM event are considered part of the acute event;

6. Neuroimaging shows focal or multifocal lesion(s), predominantly involving white matter, without radiologic evidence of previous destructive white matter changes:

a. Brain MRI, with FLAIR or T2-weighted images, reveals large (>1 to 2 cm in size) lesions that are multifocal, hyperintense, and located in the supratentorial or infratentorial white matter regions; gray matter, especially basal ganglia and thalamus, is frequently involved;

b. In rare cases, brain MR images show a large single lesion (≥ 1 to 2 cm), predominantly affecting white matter;

c. Spinal cord MRI may show confluent intramedullary lesion(s) with variable enhancement, in addition to abnormal brain MRI findings above specified.